MSN
Research for Better Medicines
Manufacturing excellence
MSN Life Sciences Pvt. Ltd.
Unit-3
ADVANCING RESEARCH.
ENABLING ACCESS.
ENHANCING HEALTH.

Capacity Enhancement or Release

MSN Life Sciences Private Limited

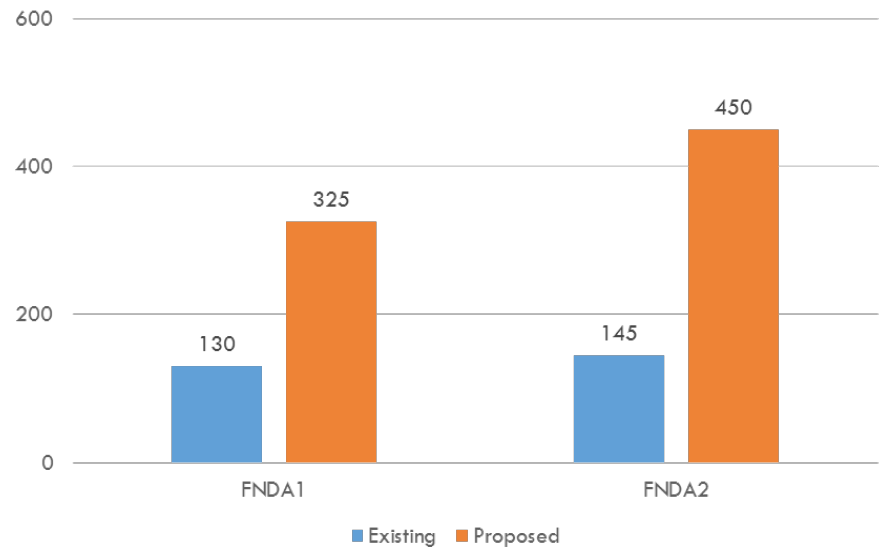
Product: Flecainide Acetate

FNDA1: Scale-up from 130 Kg to 325 Kg in existing B-Block facility,

FNDA2: Scale-up from 145 Kg to 450 Kg in existing F-Block Phase-IV.

Existing: 1.07 TPM. & **Proposed:** 4.30 TPM.

FNDA1		FNDA2	
Existing	Proposed	Existing	Proposed
130 Kg	325 Kg	145 Kg	370 Kg



Challenges:

1) Drying temperature @ 30±5°C, Acetic Acid Content spec narrow range (12.4-12.8% w/w) & Toluene removal (NMT 890 ppm)- **Dry Vacuum Pump Proposed.**

2) Coercer PSD requirement (D50- NLT 5 µm.)

Current Status:

Stage-1 (FNDA1)- Scale-up execution from 130 Kg to 325 Kg Completed in B-Block.

Stage-2 (FNDA2)- Currently Experimental batches scale-up completed up to 250 Kg scale, Further scale-up to be implemented.

Total Release of ~1795 KL Days (~60%)

Capacity Enhancement or Release

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Product:

Dabigatran Etexilate Intermediate

LDB1: 480 Kg to 640 Kg B.Size in I&C-Blocks.

LDA2: 500 Kg to 600 Kg B.Size in C-Block.

LDC1: 300 Kg to 500 Kg B.Size in C-Block.

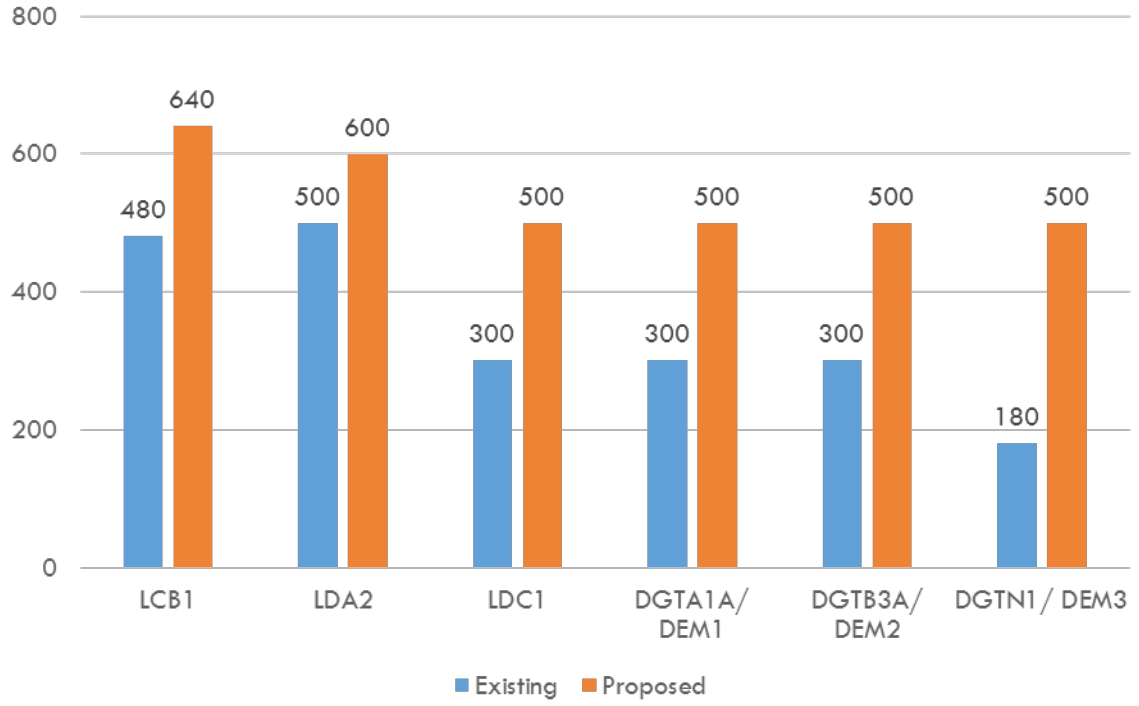
DGTA1A: 300 Kg in I-Block to 500 Kg B.Size in B-Block.

DGTB3A: 300 Kg to 500 Kg B.Size in C-Block.

DGTN1/ DEM3: 180 Kg in I&F-Blocks to 500 Kg B.Size in C-Block with additional Centrifuges installation for purifications.

Scale-up proposed to meet the monthly requirement of 5 TPM DEM3 & 14 TPM LDC1 material from LS3 Unit.

Stage	LDB1	LDA2	LDC1	DGTA1A/ DEM1	DGTB3A/ DEM2	DGTN1/ DEM3
Existing	480 Kg	500 Kg	300 Kg	300 Kg	300 Kg	180 Kg
Proposed	640 Kg	600 Kg	500 Kg	500 Kg	500 Kg	500 Kg



<u>Current Status:</u> LDB1, LDA2, LDC1, DGTA1A & DGTB3A stages scale-up Completed as per proposal. DEM3 currently 180 Kg scale batches are under process in I-Block & F-Block, 500 Kg scale-up to be implmented in next campaign.

New Products at LS-III

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New Products Status at LS-III												
S.#	Product	API Qty	Stage Code	Block	Tech Transfer	Execution						
						Trial	Validation-1	Validation-2	Validation-3	Commertial	Remarks	
1	Mesalamine	700 Kg	All Stages	B&E	Completed	Completed	Completed	Completed	Completed	Completed		
2	Vonoprazan	100 Kg	All Stages	I	Completed	Completed	Completed	Completed	Completed	Completed		
3	Chlorthalidone	500 Kg	All Stages	I	Completed	Completed	Completed	Completed	Completed	Completed		
4	Vericiguat	7 Kg	All Stages	I	Completed	Completed	Completed	Completed	Completed	Completed		
5	Finerenone	43 Kg	All Stages	I	Completed	Completed	Completed	Completed	Completed	Completed		
6	Atogepant	25 Kg	AOGT1	I	09-05-2024	Completed	Completed	Completed	Completed	U/Process	Scale-up (50 Kg to 100 Kg) Proposed in Commertial batches	
			ATGN1	I	09-05-2024	Completed	Completed	Completed	Completed	U/Process		
			AOGT2	I	27-05-2024	Completed	Completed	Completed				
			AOGT3	I	11-07-2024	Completed	Completed	To be start				
			AOGT4	I	18-07-2024	Completed	Completed					
7	Samidarphan L-Malate	15 Kg	SPLM1	I	30-03-2024	Completed	Completed	Completed	Completed	Completed		
			SPLA1	I	03-06-2024	Completed	Completed	Completed	Completed	Completed		
			SPLM2	I	08-06-2024	Completed	Completed	Completed	Completed	Completed		
			SPLM3	I	Completed	Completed	Completed	Completed	Completed	U/Process		
			SPLM4	I	Completed	Completed	Completed	Completed	Completed	U/Process		
8	Carbidopa	64/ 21 Kg	CBDP1	I	30-04-2024	Completed	Completed	Completed	Completed	NA		
			CBDP3	I	Pending							
			CBDP4	I	Pending							
9	Cannabidol	25 Kg	CNBD1		20-07-2024	Completed	To be start					
			CNBD2		15-10-2024	To be start						
			CNBD3		Pending							
10	Maribavir	15.50	MBVR1	I	29-04-2024	Completed	To be start					
			MBVR2	I	26-06-2024	To be start						
			MBVR3		Pending							
			MBVR4A		Pending							
			MBVR5A		Pending							
			MBVR6A		Pending							
			MBVA1 (Side chain)		23-07-2024	To be start						
11	Sparsentan		SRTN1B		02-05-2024	To be start						
			SRTN2B		02-07-2024							
			Remaining Stages		Pending							

Trouble shooting

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PIN MILL Trials for Levetiracetam To Meet Desired PSD	
Product & Stage:	**Levetiracetam Pharma (LVTC2)**
Existing Situation	**Requirement**
Levetiracetam Pharma material is coarser and PSD is not meeting the requirement. ~5 to 6 times Milling operation is being performed in Multimill for Sieve Top materials to meet the required PSD.	Required PSD range & Regular Trend in validations is D90 ~165 Microns.
Proposal:	
1) As the required PSD (~165 microns) is less than the multi mill mesh size (i.e. 0.25 mm/ 250 microns), material is constantly passing through miller mesh and PSD is not meeting the requirement. 2) Pin Mill Trials were performed for Levetiracetam Sieve Top material to meet the desired PSD (D90 ~165 microns) and to avoid multiple milling operation (~5-7 times)	
Results & Way forward:	
Below are the Pin Mill trail results. With 3000 RPM, D10-20.3 microns, D50-81.2 microns & D90-187 microns With 3300 RPM, D10-17.6 microns, D50-70.5 microns & D90-164 microns. Pin mill material with 3300 RPM is meeting the requirement, to be implemented in regular commercial batch. Material loss can be avoided, Effective clean room utilization & manpower by implementing Pin Mill operation in place of multiple milling operations (5-7 times).	

Filtration Optimization in Slow Filtration areas

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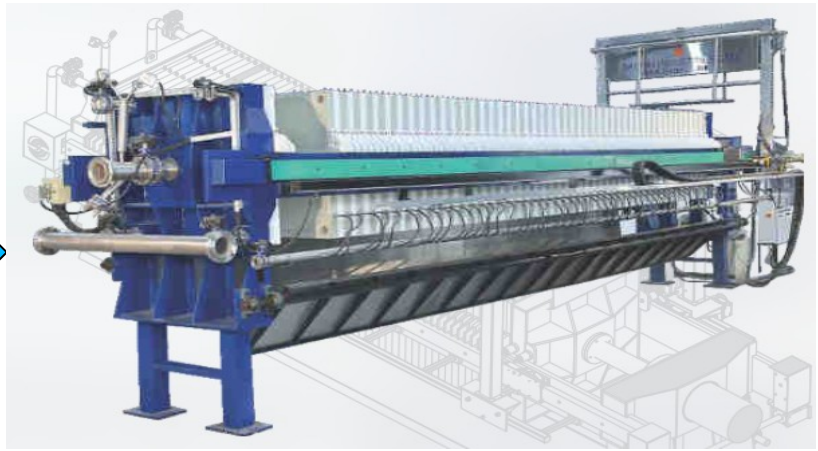

Challenges in Existing Open Nutsche Filter:

- Existing Filter Capacity- 1.0 KL x 2 Nos of Open Nutsche Filters.
- Rate of Filtration & filtration flux is slow (<20 LPM/m2) due to slimy nature of unwanted salt resulting in impact on productivity.
- Filtration in hot condition 45-50°C & Reaction mass is mixture of Water + Toluene resulting in potential fire hazard during handling.

Advantages in Membrane Press Filter:

- Rate of Filtration & filtration flux will be more in proposed Filter Press.
- Process cycle time will be reduced due to more filtration area.
- Reduces the wash water consumption.

Current Status: Membrane Press Filter 15 m2 area (1000 mm x 1000 mm) received & installation u/process at I-Block.

Customer Support for PSD

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S.#	Block	Product	Activity	Status	Remarks
1	F-Block	Opicapone	2.0 Kg x 2 Nos Samples for ABBOTT with Below PSD Specifications. **Fine Material (2 Kg):** D(95): Not more than 10 µm D(50): Not more than 6 µm D(10): Not more than 4 µm **Coarser Material (2 Kg):** D(95): Not more than 70 µm D(50): Between 10-45 µm D(10): Not less than 4 µm	Existing Material PSD Trend is D(95) : 11-14 µm D(50) : 4-5 µm D(10) : 2-3 µm **Fine Material (2 Kg):** Micronized material with 0.6 ± 0.2 Kg/cm2 feed & chamber pressure is meeting the requirement, Dispatch completed. **Coarser Material (2 Kg):** Batch executed at Pilot plant with modified process & material dispatched with coarser specification.	
2	F-Block	Mesalamine	MSNF requirement for 6.0 Kg x 2 Nos with below PSD specifications. **Coarser Material (2 Kg):** D(90): 50-100 µm **Fine Material (2 Kg):** D(90): Below 10 µm	**Coarser Material (2 Kg):** Material with Additional Milling operation (0.5 mm mesh & full RPM) is meeting the specification. Material dispatched with D90- 82 µm **Fine Material (2 Kg):** Micronization trial with 6.5 ± 0.2 Kg/cm2 feed & chamber pressure is meeting the required specification. Analysis Under Process (D90- 6.8 µm) & Material	

THANK YOU!

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